REMARKS/ARGUMENTS

Claims 1, 3, 6-9, 11, 13, 19-22, and 33-37 and 39-40 are now pending, a total of 19 claims. Independent claims 1, 9, and 33 are currently amended. Support for the amendments can be found, for example, on pages 4 and 5 of the specification as filed. Claims 2, 4-5, 10, 12, 14-18, 23-32, 38 and 41 are canceled.

I. Claim Objections

Claims 1, 3, 6-9, 11, 13, 19-22, 33-37, and 39-40 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. These claims have been amended to recite that the restriction "has an inner diameter with a ratio of about 0.93 or more," which is disclosed in the specification as discussed by the Examiner in the Office Action. Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner also rejected claims 1 and 9 on the argument that these claims recite an element ("only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin") that is narrower than the original supporting disclosure. However, as quoted by the Examiner, page 2 of the specification recites that a polyethylene fluoride resin can be applied on "the peripheral side surface that is contact with the inner surface of the syringe barrel ***and/or*** a bottom surface that is in contact with liquid" (emphasis added). This "and/or" language clearly discloses that the resin can be applied selectively to the peripheral side surface. Support for this recited element is also on page 3 of the specification, which recites that "[t]he peripheral side surface that is in contact with the syringe barrel or the bottom surface that is in contact with liquid can be laminated with polyethylene fluoride resin . . .". (Specification, p. 3, lines 12-14.) Accordingly, withdrawal of this rejection is respectfully requested.

II. Claim Rejections - 35 U.S.C. § 103

A. Claims 1, 3, 6-9, and 19-22: Trull in view of Ivey, Sudo and Akaike

Claims 1, 3, 6-9 and 19-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136) in view of Ivey (U.S. 5,976,299) and further in view of Sudo et al. (U.S. 5,009,646) and further in view of Akaike et al. (5,061,247). Applicant respectfully disagrees with Examiner's position that one of skill in the art would find it obvious to combine the teachings of Trull, Ivey, Sudo and Akaike to meet all of the recited elements of the claimed invention.

The Office Action states that Ivey teaches the use of polyethylene film to make "sterilizable receptacles for medical use, including syringes". Applicant respectfully submits that this is a misunderstanding of Ivey, as the "receptacles" in Ivey are sterilizable bags into which medical instruments such as syringes can be packaged. See Ivey, col. 1, lines 13-24; Ivey, col. 4, lines 41-44 ("The invention is related to a sterilizable receptacle for articles used in intermediate processing by the pharmaceutical industry. In particular, the preferred embodiment of the receptacle is a bag, or pouch . . ."). Thus, neither Ivey nor any of the other references cited by the Examiner disclose, teach or suggest a syringe having a "barrel composed of a annular polyolefin resin" as recited in the present claims.

The Examiner argues that the recited range of hardness is obvious in light of Akaike. However, as detailed in the Declaration of Keizou Nakamoto (submitted concurrently), experimental data showed that gaskets having the recited JIS hardness achieved unexpectedly superior results over gaskets having a hardness outside the recited range but within the range of Akaike (*See* Nakamoto Decl., ¶15.) Remarkably, experimental testing showed that failures for three different quality-control tests were virtually eliminated for gaskets having the recited hardness, while gaskets having a hardness outside the recited range but within the range of Akaike failed at a rate of almost 50% for some of the tests. (*See* Nakamoto Decl., ¶¶13-15.) Thus, even if the Examiner's combination of Akaike with the other cited references presented a

prima facie case of obviousness, this *prima facie* case has been rebutted by a showing of unexpected results. *See, e.g., In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995); MPEP 716.02(a).

With respect to Sudo, Applicant respectfully disagrees that Sudo teaches or suggests a specific relationship between the diameters of the gasket and a restriction thereof; rather, Sudo discusses the ratio between the diameter of the gasket and its length. *See, e.g.*, Sudo, col. 3, lines 3-22 and Fig. 2. Furthermore, Applicant respectfully continues to disagree that MPEP 2144.04(2)(a) is applicable in the present case with respect to Sudo. MPEP 2144.04(2)(a) is directed to the omission of separate and distinct elements. In contrast, Sudo teaches that the gasket is fully laminated, with the lamination of the peripheral side and the side contacting the fluid being formed from one piece simultaneously with the forming of the gasket (*see, e.g.*, Sudo, col. 3, lines 61-66). Thus, it would not be obvious to meet the limitations recited in the present claim 1 by modifying the laminated layer as taught in Sudo.

For at least the reasons discussed above, the cited references do not teach or suggest a laminated gasket with restriction with a syringe barrel composed of a polyethylene fiber as recited in claims 1, 3, 6-9 and 19-22. Accordingly, Applicant requests withdrawal of the rejections under 35 U.S.C. § 103(a) with respect to independent claims 1, 3, 6-9 and 19-22.

B. Claims 11 and 13: Trull in view of Sudo, Ivey and Akaike and further in view of Higashikawa

Dependent claims 11 and 13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull in view of Sudo, Ivey and Akaike and further in view of Higashikawa (U.S. 5,830,193). In light of the present amendments and arguments above, it is respectfully submitted that these dependent claims are also patentable with their respective independent claims as set forth above, and recite additional features that further distinguish the invention. Accordingly, Applicant requests withdrawal of the rejections under 35 U.S.C. § 103(a) with respect to independent claims 11 and 13.

C. Claims 33-37 and 39-40: Trull in view of Sudo, Ivey and Akaike and further in view of Vacca

Claims 33-37 and 39-40 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull in view of Sudo, Ivey and Akaike and further in view of Vacca (U.S. 5,531,255).

For the reasons discussed above, it is respectfully submitted that independent claim 33, as amended, is patentable over the cited references. It is also respectfully submitted that dependent claims 34-37 and 39-40 are patentable with independent claim 33 as set forth above. These dependent claims recite additional features that further distinguish the invention. Accordingly, Applicant requests withdrawal of the rejections under 35 U.S.C. § 103(a) with respect to independent claims 33-37 and 39-40.

In view of the foregoing, Applicant respectfully submits that the pending claims are in condition for allowance and requests reconsideration of the application. The Examiner may telephone Applicant's undersigned counsel at the number below concerning this application.

No fee is believed to be due with this response. Should any fee be due, kindly charge such fee and any additional fees to Deposit Account No. 23-2405, Order No. 114474.00014.

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